K971379

JUN 17 1997

BOEHRINGER MANNHEIM CORPORATION

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter name, address, contact

Boehringer Mannheim Corporation
2400 Bisso Lane
P.O. Box 4117
Concord, CA 94524-4117
(510) 674 - 0690, extension 8413
Fax: (510) 687-1850

Contact Person: Yvette Lloyd

Date Prepared: April 8, 1997

2. Device name

Proprietary name: Tina-quant® Rheumatoid Factor Assay

Common name: Immunoturbidometric assay for the determination of Rheumatoid Factor.

Classification name: Rheumatoid Factor immunological test system

3. Predicate device

The Boehringer Mannheim Tina-quant® Rheumatoid Factor assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Behring Laser Rf Test - Rheumatoid Factor (S) Reagents (K850296).

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4. Device Description

The Rheumatoid Factor determination is based upon turbidimetric immunoinhibition (TINIA) using a serum or plasma blood sample. The sample containing rheumatoid factor is transferred into a buffer solution (R_1 reagent). In the second step, an aliquot of solution containing fine latex particles coated with polyclonal human IgG (anti-human rheumatoid factor antibodies - R_2 reagent) is added to mixture of the first step. The antibody-coated particles will bind to the rheumatoid factor in the sample to form "aggregates" such that the amount of aggregate formed is proportionate to the amount of rheumatoid factor present in the sample.

The resulting agglutination complex is measured turbidimetrically whereby increased turbidity is reflected through an increase in optical density. Therefore, the amount of rheumatoid factor in the sample is directly proportional to the amount of turbidity formed.

5. Intended use

Immunoturbidometric assay for the quantitative in-vitro determination of rheumatoid factor.

6. Comparison to predicate device

The Boehringer Mannheim Tina-quant® Rheumatoid Factor assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Behring Laser Rf Test - Rheumatoid Factor (S) Reagents (K850296).

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6. Comparison to predicate device cont.

The following table compares the Tina-quant® Rheumatoid Factor with the predicate device, Behring Laser Rf Test - Rheumatoid Factor (S) Reagents. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

Similarities:

- Intended Use: Immunoassay for the in vitro quantitative determination of Rheumatoid Factor.
- Sample type: Serum and plasma

Differences:

Feature	Tina-quant® Rheumatoid Factor	Laser Rf Test - Rheumatoid Factor (S) Reagents
Reaction test principle	Immunoturbidimetric	Laser Nephelometry
Instrument required	Hitachi 717	Behring Laser Nephelometer

Performance Characteristics:

Feature	Tina-quant® Rheumatoid Factor			Laser Rf Test - Rheumatoid Factor (S) Reagents		
Precision	Intra and InterAssay (IU/mL):			Intra and Interassay (IU/mL):		
Level	Sample 1	Sample 2	Sample 3	Low	Mid	High
N	21	21	21	20	20	20
Intra-Assay Mean	31.9	144.4	645.1	52	201	510
%CV	3.8	1.4	1.1	range 4.2 to 6.1%		
Level	Sample 1	Sample 2				
Inter-Assay Mean	76.4	347.4		92	155	306
%CV	2.6	2.2		9.3	6.2	6.6

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Tina-quant® Rheumatoid Factor	Laser Rf Test - Rheumatoid Factor (S) Reagents
Lower Detection Limit	7.5 IU/mL	10 IU/mL
Linearity	7.5 - 140 IU/mL	10 - 600 IU/mL
Method Comparison	Vs Behring Laser Nephelometer RF Passing/Bablok y =1.01x - 2.30 r=0.880 SEE =11.20 N=35 Least Squares: y = 0.90x + 5.11 r = 0.880 SEE = 15.32 N = 35	Vs NA Latex RF Kit Regression: y =0.90x - 20 r=0.975 SEE =44.9 N=72

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Tina-quant® Rheumatoid Factor	Laser Rf Test - Rheumatoid Factor (S) Reagents
Interfering substances	No interference at: (≤ 10% error)	No interference at:
Bilirubin	30 mg/dL	not tested
Hemoglobin	20 g/L	2 g/dL
Lipemia	2000 mg/dL	not tested

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 17 1997

Ms. Yvette Lloyd
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
2400 Bisso Lane
Concord, California 94524-4117

Re: K971379
Trade Name: Tina-quant® Rheumatoid Factor Reagents
Regulatory Class: II
Product Code: DHR
Dated: April 8, 1997
Received: April 14, 1997

Dear Ms. Lloyd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): N/A

Device Name: Tina-quant® Rheumatoid Factor Assay

Indications For Use:

The Tinaquant Rheumatoid Factor assay is an immunoturbidometric assay for the quantitative determination of rheumatoid factor (antibodies to immunoglobulins) in human serum or plasma using automated clinical chemistry analyzers. Measurement of rheumatoid factor may be used as an aid in the diagnosis of rheumatoid arthritis.

Peter E Maggiore

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)